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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,836	05/16/2001	Han Oh Park	024018/0105	9171

7590

11/19/2002

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EXAMINER

WARE, DEBORAH K

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/855,836

Applicant(s)

Park et al.

Examiner

Deborah Ware

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1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 29, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above, claim(s) 16-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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Claims 1-45 are presented for reconsideration on the merits.

The amendment filed April 18, 2002 and supplemental response and declaration filed May 13, 2002, have been received. The declaration provided under 35 USC 1.132 has been considered, accordingly. Thus, the deposits under Budapest Treaty have been recognized and the rejection under 35 USC 112, first paragraph has been removed.

1. Applicant's election with traverse of Group I, claims 1-15, in Paper No. 11 is acknowledged. The traversal is on the ground(s) that there is no serious burden placed upon the examiner. This is not found persuasive because for reasons of record, each of the independent invention(s) are classified in different classes and subclasses, therefore, based upon the extensive search for each and every invention a serious burden is placed upon the examiner. Based upon the initial search and the updated search on the basis of the election this even becomes more evident that a serious burden does indeed exist for the examiner to provide a search for more than one invention. Thus, the restriction requirement has been reconsidered as requested by Applicants but it is deemed to be necessary in this case, however, Applicants are correct that it is possible that all claims may be rejoined upon the indication of allowable subject matter, although examiner's amendment may be needed to place all claims being rejoined within the scope of the indicated allowable subject matter.

The requirement is still deemed proper and is therefore made FINAL.

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2. Claims 16-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 11.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

OK  
D The specification is objected to because at page 32, the depository address appears to have been omitted, and Applicants are requested to amend the specification at page 32, at paragraph [0270] in an appropriate place therein to provide for the address of the Korean depository. This is in order that the specification be in accordance with 37 CFR 1.809(d)(4).

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6 & 13 for  
prior art

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obj. to:  
6 mly  
13 only

4. Claims 1, 3-7 and 10-14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over newly cited Sawada et al. (A).

3-5, 7 & 10-12 & 14.

Claims are drawn to a biologically pure strain of *Lactobacillus* sp. and pharmaceutical, which is a formulation suitable for oral administration containing an effective amount of the same microorganism capable of producing a polysaccharide. A carrier contained within said composition is also claimed.

Sawada et al. (Sawada) teach biologically pure strain of *Lactobacillus* sp. and pharmaceutical, which is a formulation suitable for oral administration containing an effective amount of the same microorganism capable of producing a polysaccharide. Note col. 2, lines 27-30, col. 3, lines 55-65, and col. 4, lines 60-65. A carrier such as a liquid carrier (i.e orange juice) is disclosed, note col. 10, lines 55-62.

The arguments set forth at page 5, of Applicants' amendment filed April 18, 2002, are noted, however, the claims discussed above are directed to a product wherein the intended use of that product is not necessarily given any patentable weight and the product as claimed must stand on its own merits based upon the ingredients contained by the product. The newly cited prior art clearly teaches the same products as claimed herein and thus, the claims are considered to be anticipated by the teachings of the cited reference. However, in the alternative that there is some unidentified claim characteristic for which provides for some difference then the difference is considered to be so slight as to render the claims *prima facie* obvious over the cited prior art. Wherein one of skill would have been motivated by the teachings of the reference to isolate a

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1-2 } for + indicat @  
6, 13 } see.  
Novel strains to 6813  
but obj. dec. depend on ref base c/m/s

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Lactabacillus sp. and to use such microorganism in a pharmaceutical as claimed herein because the teachings of the cited reference does indeed teach these features for which the claims are directed to. The claims are at least obvious over the cited prior art.

3-5, 7-9 & 10-12 & 14-15  
5. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawada et al., as cited above, in view of newly cited Becker et al. (B) and if necessary in further view of Toyosaki et al., cited on the previously submitted PTO-1449 Form.

3-5  
6  
7-9  
4  
These claims are directed to as discussed above but in addition to a formulation coated with enteric coating materials.

Sawada is discussed above.

Becker et al. (Becker) is directed to a pharmaceutical or medicament which is defined as a dietary fiber of which is more particularly defined as the polysaccharides derived from cell wall content, note col. 4, lines 30-68, and the pharmaceutical has an intended use of treating and/or preventing diabetes and obesity, note col. 4, line 53 and 68 and lines 50-53. More significantly, the reference provides for a teaching of a formulation coated with enteric coating materials. Note the abstract too, and col. 5, lines 5-45 and col. 6, lines 30-40.

Toyosaki et al. (Toyosaki) clearly teach Acetobacter strain capable of producing a polysaccharide. Note pages 1498-99, all lines.

The claims differ from the teachings of Sawada et al. in that the intended use of treating and/or preventing diabetes and obesity and a formulation coated with enteric coating materials is

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not disclosed; nor is a strain of *Acetobacter* or one capable of producing a polysaccharide for use in the formulation.

It would have obvious to one of ordinary skill in the art at the time the claimed invention was filed to combine the teachings of Sawada et al. and Becker to obtain a formulation coated with enteric coating materials for the intended therapeutic uses of treating diabetes or obesity as the polysaccharides produced by the microorganisms of both Sawada and Becker are taught to provide the same uses for treatment of diabetes and obesity and furthermore, to enterically coat the formulation with coating materials taught by Becker would have been an obvious modification of Sawada. One of skill would have been motivated by the teachings of the combined references wherein in each reference it is taught that the formulation is orally delivered. Therefore, one of skill would have expected successful results for making the modification of Sawada to provide for the enteric coated formulation as disclosed by Becker. Clearly the pharmaceuticals are well recognized in the cited prior art. Also *Acetobacter* as disclosed by Toyosaki produces a polysaccharide and would have been expected to provide successful results by formulating it into a pharmaceutical as well. To select for at least one microorganism for the pharmaceutical is clearly disclosed by the cited prior art. Thus, in the absence of a side by side comparison of the microorganism strains so claimed from those of the cited prior art to establish that the microorganisms would not have been expected to provide successful results by some difference of these claimed microorganism strains, the claims are *prima facie* obvious over the cited prior art.

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*2* *o/c remove based on applicant's responses*  
6. Claim 2 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Toyosaki et al.

*NO response by applicants must be individually*  
7. Claim is drawn to a strain of Acetobacter.

8. Toyosaki discussed above teaches strain(s) of Acetobacter.


9. The claim is identical to the disclosure of Toyosaki and is considered to be anticipated by the teachings therein. However, in the alternative that there is some difference between the claimed subject matter and the disclosure then such difference is considered to be so slight as to render the claim obvious over the reference. Applicants' argument are noted, however, the Toyosaki disclosure clearly teaches that the strain of Acetobacter is capable of producing a polysaccharide, thus, Applicants' claimed strain fails to adequately distinguish over the cited disclosure. The strains appear to be identical, or at least obvious, if there is some slight difference of which is not apparent in the claim. One of skill would have at least been motivated by the teachings of the cited prior art to isolate an Acetobacter strain. The claim alternatively is prima facie obvious over the cited reference. Applicants' arguments are noted, however, the strains of the prior art do also produce polysaccharide and thus no other characteristics have been established for the claimed strain for which to distinguish the claimed strains from the cited prior art.

10. All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

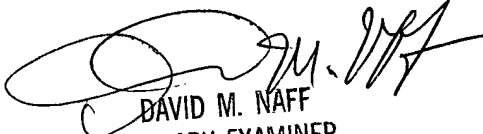


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11. The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.
12. No claims are allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.
14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.
15. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Deborah K. Ware

November 17, 2002

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 1651